News Releases

Closing the Gap: Malaria Vaccine Candidate Proves to Be Effective in Navy Medicine Clinical Trial

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2016126-N-LJ212-008 SILVER SPRING, Md (Dec. 6 2016) Capt. Judith Epstein,, Md (Dec. 6 2016) Capt. Judith Epstein, Clinical Director of the Naval Medical Research Center (NMRC) Malaria Vaccine Development Program, fills out a record book in the Clinical Trials Center regarding work being done to develop a malaria vaccine for the warfighter. (U.S. Navy Photo by Public Affairs Specialist, Katie Berland NMRC/Released)

SILVER SPRING, Md. – In recent years, researchers at the Naval Medical Research Center (NMRC) and the Walter Reed Army Institute of Research (WRAIR) have put much effort into developing an effective and safe vaccine against malaria – a disease that is ranked by the Department of Defense (DoD) as the number one infectious disease threat to military personnel deployed to areas where it is endemic.

The paper, *Protection Against Plasmodium falciparum Malaria by PfSPZ Vaccine,* published in *JCI Insight,* January 12, 2017, highlights the research conducted by a team of clinical investigators at NMRC and WRAIR, led by Navy Capt. Judith Epstein and Army Maj. Kris Paolino, now retired. The study reports that a radiation-attenuated *Plasmodium falciparum* (Pf) sporozoite (SPZ) malaria vaccine, PfSPZ Vaccine, developed by NMRC collaborative business partner, Sanaria, protected volunteers against two strains of *Plasmodium falciparum* malaria. The sporozoite is the stage of the malaria parasite which an infected mosquito injects into a person. The PfSPZ Vaccine includes parasites that are attenuated, or weakened; they generate strong immune responses against malaria, but cannot cause disease.

"As a Navy scientist it has been rewarding to work hand-in-hand with Army investigators as we move closer to the goal of a vaccine that can provide protection against malaria for our military personnel," said Epstein. "Many experts believe that this vaccine may be used to protect the most vulnerable populations abroad and in mass vaccination administration campaigns to eliminate the disease."

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A recent clinical trial assessed tolerability, safety, immunogenicity and protective efficacy of the vaccine in non-immune subjects. The clinical trial included 67 subjects, 19 to 45 years old. Of the 67 subjects, 45 received at least one dose of the vaccine, and 22 were control subjects.

Initial studies demonstrated that five doses of PfSPZ vaccine provided protection against infection by malaria parasites similar to those used in the vaccine in six of six subjects (100 percent) who were tested three weeks after the final vaccine by exposure to malaria-infected mosquitoes in a Controlled Human Malaria Infection, (CHMI).

Three weeks after last immunization, 25 of the 28 subjects (89 percent) were protected against infection by malaria parasites similar to those in the vaccine that were transmitted by exposure to malaria-infected mosquitoes in the CHMI. Four out of five vaccinated subjects were protected against infection by parasites different from those in the vaccine. Twenty-four weeks after last dose of vaccine, 15 of 24 subjects (63 percent) were protected against parasites similar to those in the vaccine. In addition to achieving protection with just three doses of the vaccine and against a strain of parasite similar to the one in the vaccine for at least 24 weeks, PfSPZ Vaccine was well tolerated, safe, and easy to administer.

According to the Centers for Disease Control and Prevention (CDC), “people who get malaria are typically very sick with high fevers, shaking chills, and flu-like illness. Although malaria can be a deadly disease, illness and death from malaria can usually be prevented.”

According to the World Health Organization, African children are hardest hit, and the disease primarily affects individuals in 17 African nations, with those in the Democratic Republic of Congo and Nigeria most often infected.

A highly effective malaria vaccine would be an ideal tool to prevent malaria in travelers and deployed military, reduce morbidity and mortality in infants and children, and eliminate malaria from defined geographic areas through mass vaccine administration campaigns.

“We are excited that this research backs up our hopes for the vaccine,” said Epstein. “With this research, and future vaccine research, we believe that we may finally be able to close the gap between wanting to protect against malaria, and having the actual capabilities to do so”

The clinical trial reported today in JCI Insight was supported by the U.S. Department of Defense (DoD) through the Joint Warfighter Medical Research Program, the Military Infectious Diseases Research Program, and U.S. Navy Advanced Medical Development and other sponsors.

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